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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,008	08/11/2005	Mark A. Atkinson	36689.42	4535

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1633	
MAIL DATE	**DELIVERY MODE**
12/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/512,008	ATKINSON ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,11,13,14,17,19,20,24,32-42,46 and 47* is/are pending in the application.

4a) Of the above claim(s) *33-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,11,13,14,17,19,20,46 and 47* is/are rejected.

7)☒ Claim(s) *24,32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070911*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Claims 33-42 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/30/07.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required. Claim 46 recites "mammalian β-actin promoter". This term does not appear in the specification as filed, but appeared only in original claim 10. The term is not new matter, it simply needs to be added to the specification to provide the antecedent basis, although at a location that does not introduce new matter due to the context in which it is inserted.

Claim Objections

Claims 24 and 32 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend from a multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 24 and 32 have not been further treated on the

merits. Claims 24 and 32 depend from claim 20, which has been amended to be a multiple dependent claim.

Claim 46 is objected to because of the following informalities: claim 46 recites "IL-10 I87A", which should be --IL-10(I87A)--, as in Fig. 14 and in claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to recite that the promoter is one that mediates expression in mammalian pancreatic islet cells. Claim 10 has been amended to recite "chicken β-actin promoter" in the context of claim 1, and claim 11 has been amended to recite liver-, lung-, muscle-, kidney- , or pancreas-specific enhancers, also in context of claim 1. Applicant has not indicated where and how the original disclosure supports this new juxtaposition of claim elements, as is Applicant's burden. See MPEP 714.02, last sentence of the third paragraph from

the end and 2163.06 (I) last sentence. There is no clear support in the original disclosure for an rAAV comprising a "chicken β-actin promoter". Rather the original disclosure describes hybrid promoters comprising a "chicken β-actin promoter" and CMV enhancer. There is also no clear support in the original disclosure for an rAAV comprising a promoter that mediates expression in mammalian pancreatic islet cells and a liver-, lung-, muscle-, kidney- or pancreas-specific enhancer. With respect to the latter, not all pancreatic cells are islet cells. As a results, these claims now contain impermissible new matter.

Claim Rejections - 35 USC § 102

Claims 1, 11, 13, 17, 19, and 20 remain rejected under 35 U.S.C. 102(a) as being anticipated by Yamano et al. (J. Gene Med. 3: 450-457, 02 Aug. 2001), as evidenced by Muzyczka et al., US 6,020,192 for the reasons of record set forth in the Office action of 4/27/07.

Applicant's arguments filed 10/29/07 have been fully considered but they are not persuasive. Applicant's intent to file a declaration under 37 CFR 1.131 is noted. However, no such declaration has been received.

Claims 1, 10, 11, 13, 14, 17, 19, 20, 46, and 47 remain rejected under 35 U.S.C. 102(e) as being anticipated by Loiler et al., US 2006/0292117 for the reasons of record set forth in the Office action of 4/27/07.

With respect to amended claim 10, Loiler specifically teaches using a chicken β-actin promoter operably linked to an IL-10 or IL-10 (I87A) gene in a vector to transfect islet cells.

Applicant's arguments filed 10/29/07 have been fully considered but they are not persuasive. Applicant's intent to file a declaration under 37 CFR 1.132 is noted. However, no such declaration has been received.

Claims 1, 11, 13, 14, 17, 19, and 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Hildinger et al., US 7,056,502 for the reasons of record set forth in the Office action of 4/27/07.

Applicant's arguments filed 10/29/07 have been fully considered but they are not persuasive. Applicant argues that Hildinger does not disclose an rAAV "comprising a polynucleotide (*sic*) that expresses in *human pancreatic islet cells*, a biologically-active IL-10 or IL-10(I87A) protein". In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that one feature upon which applicant relies (i.e., expresses in human pancreatic islet cells) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). More importantly, as pointed out in the rejection the promoters of Hildinger indicated in the rejection are general promoters that mediate expression in a wide variety of cell types, including mammalian pancreatic islet cells, especially the CMV promoter. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

Claims 46 and 47 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hildinger et al., US 7,056,502, as applied to claims 1, 11, 13, 14, 17, 19, and 20 above, and further in view of Xiao et al., US 6,329,181, and of PIR Acc. No. A25946 or PIR Acc. No. A38580 for the reasons of record set forth in the Office action of 4/27/07. (This rejection has been rewritten to include the intervening rejection of claim 10 over Hildinger and Xiao, which was incorporated by reference in this rejection in the preceding Office action).

Hildinger has been described. Hildinger teaches AAV vectors with a generic β-actin promoter, but not specifically a mammalian β-actin promoter.

However, Xiao describes AAV vectors generally, and particular methods of making them. It teaches a variety of promoters that can be used in AAV vectors, and specifically teaches that the human β-actin promoter is a ubiquitous, constitutive promoter suitable for use in AAV vectors (col. 15, lines 53-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the human β-actin promoter, taught by Xiao, as the β-actin promoter in the AAV vector of Hildinger, since Xiao taught that the human β-actin promoter was a suitable promoter for use in an AAV vector. See MPEP 2144.07.

Hildinger and Xiao are described above. Hildinger discloses that a primary use of the AAV vector is for delivery of the transgene carried in the vector to a human, such as in gene therapy (see Hildinger at col. 16, for example). Although Hildinger discloses an AAV vector expressing IL-4 or IL-10, it does not teach that the sequences the IL-4 and IL-10 should be that of SEQ ID NOs: 1 (human IL-10) or 3 (human IL-4).

PIR Acc. No. A25946 or PIR Acc. No. A38580, which are disclosed in the instant specification on page 108 and assigned SEQ ID NOs: 3 and 1, respectively, show the sequences of human IL-4 and IL-10 were known in the prior art.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the AAV vector to have been made to express the human IL-4 or IL-10 shown in instant SEQ ID NOs: 1 or 3. Hildinger taught that one use of the AAV vector was for expression of the protein, such as IL-4 or IL-10, in a human, and the sequence for the human IL-4 and IL-10 was known. One of skill in the art of human gene therapy would understand that expression of the endogenous human protein would present fewer potential side effects than expression of an IL-4 or IL-10 from another organism.

Applicant's arguments filed 10/29/07 have been fully considered but they are not persuasive. In response to Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., rAAV comprising a chicken β-actin promoter) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claims 46 and 47 require a "mammalian β-actin promoter" (line 2), and not a "chicken β-actin promoter" as argued.

Conclusion

Applicant's request for an interview is noted. However, Applicant presents no specific issues that would be the subject of such an interview, and did not request that the Examiner delay

action on Applicant's reply to the previous Office action. It is not evident to the Examiner that an interview prior to Applicant's consideration of this final rejection would serve to advance prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633